UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,024	04/06/2005	Tetsuo Santo	JCLA14658	8756

23900 7590 05/16/2008

J C PATENTS, INC.
4 VENTURE, SUITE 250
IRVINE, CA 92618

EXAMINER	
CLARK, AMY LYNN	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,024	SANTO ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 14* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 11 July 2007with the amendment of claims 1-9, and newly added claims 14.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 1-9 and 14 are currently pending.

Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/13/2006.

Claims 1-5, 7-9 and 14 are currently under examination.

Drawings

The drawings were received on 11 July 2007. These drawings are acceptable.

Specification

The disclosure is objected to because of the following informalities: The specification refers back to certain claims (See pages 7, 9, 10 and 15-19 of the originally filed specification). Please delete the word "claim" and its number wherever it appears in the specification, since the specification should not refer to claim numbers, due to the fact that more often than not, claims are amended, cancelled or modified in

some way that makes them different from those originally filed. Therefore, referring back to originally filed claims in the specification as part of the disclosure is not appropriate. There are several parts of the specification that are missing spaces between words. For example, on page 2, lines 4, of the originally filed specification. Please note that the Examiner has not pointed out every instance where this error occurs. Applicants should go through the entire specification and make these corrections where necessary. Finally, Example 1 in the originally filed specification, contains the word "tee", which is misspelled. It should be corrected to read tea. Appropriate correction is required.

Claim Objections

Claims 1-3 are objected to because of the following informalities: please correct all of the Latin names of the plants used to follow the following format: *Sophora flavescens* Ait. and *Isatis tinctoria*. The first Latin word in each name is capitalized and the second Latin word in each name is lower case. Both the first and second Latin word should be italicized and if there is a third abbreviated word in the Latin name, it should be capitalized without italics. Follow the template provided above and correct all Latin names provided in claims 1-3. Appropriate correction is required.

Claim 8 is objected to because of the following informalities: please correct "Lighospermum" in line 10 to read lithospermum and "Lucorice" in line 11 to read licorice. Appropriate correction is required.

Claim14 is objected to because of the following informalities: please either delete the word “are” from line 2 or add which between “extracts” and “are” in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *"whatever is now claimed"* (See page 1117).

A review of the language of the claim indicates that these claims are drawn to "A tea for treating dermatitis comprising: extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" in claims 1, 2, 4, 5, 8 and 9,

and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice" in claim 3 and all of the ingredients of claim 3, which are listed in claims 8, 9 and 14.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". Hence, an adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an

invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing "extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" , and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice", in the absence of knowledge as to what the material consists of or the source of the material is not a description of the material.

In the instant case, on pages 7 and 8, the originally filed specification discloses that "the families and tastes, main components and principal activities of the plants as raw materials for the above-mentioned respective extracts drawn from plants are described briefly in the following" and then Applicants provide a list of the instantly claimed plants and further characterize what their main active components are and the main activity of the plant". Please note that Applicants are merely stating that these components are "raw materials for the above mentioned respective extracts" and are not describing the actual extract itself.

The originally filed specification further discloses that "this drinkable tea may be taken in the liquid form of extracts itself drawn from medicinal herbs, or in a once pulverized or granulated form together with water or hot water. When it is in a powdery or granular form, the drinkable tea may be contained in a cavity of mouth before taking hot water or water like the conventional powdery or granular drinkable tea, or it may be

taken after once dissolving in hot water or water". Again, Applicants are not describing what Applicants regard as the extract but rather how the extract can be used, which is not the same thing as how to obtain the extract or what the extract is.

Other than the compositions and examples of specific herbs used, wherein the originally filed specification simply discloses, extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.), and extracts of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice, without disclosing what Applicants regard as an extract of each of these plants, the specification fails to adequately describe as to what Applicant defines or considers as "extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" , and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice". Nowhere in the present specification does Applicant render a definition of the term "extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" , and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice" nor do Applicants cite an example of this term thereof. Furthermore, Applicants do not provide any method of

making or obtaining the extracts claimed and disclosed in the specification, nor do Applicants provide any guidance as to what Applicants regard as "extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" , and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice". Please note that there are many types of extracts possible and each type of solvent used would provide different active ingredients (for example, a polar solvent would provide a very different extract than a non-polar solvent). There are also many different types of extraction, such as steam distillation, solvent extraction, supercritical extraction, etc. and these methods would also provide different active ingredients and types of extracts.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of what constitutes "extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" , and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice". The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description

provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claims 1-5, 7-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.), and extracts obtained from Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice, which are critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Applicant discloses a drinkable tea in which the weights of extracts ingredients drawn from respective medical herbs per g of a drinkable tea in the form of powders or granules are: Lightyellow Sophora Root, 0.1 g; Isatis Leaf, 0.1 g; and Terminalia Fruit, 0.02 g; Japanese Angelica Root, 0.05 g; Oldenlandia diffusa, 0.1 g; Smilax Glabra, 0.12 g; Dried Tangerine Peel, 0.05 g; Wild Chrysanthemum Flower, 0.1 g; Corydalis, 0.02 g; Peppermint, 0.01 g; Baikal Skullcap, 0.05 g; Lithospermum, 0.1 g; Kudingcha, 0.05 g; Smartweed, 0.1 g; and Licorice, 0.03 g, as a working example; however, it should be noted that Applicant does not provide guidance in the specification as to how to make the exemplified drinkable tea in the form of powders or granules comprising: Lightyellow Sophora Root, Isatis Leaf, Terminalia Fruit (which is not even mentioned in the newly amended claims and was not elected in response to the election restriction requirement mailed out on 06/27/2006, but appears to be an essential ingredient in the preferred

embodiments), Japanese Angelica Root, Oldenlandia diffusa, Smilax Glabra, Dried Tangerine Peel, Wild Chrysanthemum Flower, Corydalis, Peppermint, Baikal Skullcap, Lithospermum, Kudingcha, Smartweed, and Licorice. Nor does Applicant provide guidance in the specification of how to make the instantly claimed extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.), Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice. Therefore, it is unclear as to what combination of ingredients Applicant has combined to provide the exemplified composition. Based on what was known in the art at the time the invention was made, lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.), were known to be useful in treating dermatitis and psoriasis, as was that the other exemplified ingredients in the originally filed specification were also useful for the same purpose. However, the art does not describe extracts of these plants for this use, but rather the plants themselves. In the absence of what each ingredient is and how each ingredient is obtained, it is unclear as to what Applicants are enabled for. Therefore, Claims 1-5, 7-9 and 14 are not considered to be enabled by the instant specification.

Claims 1-5, 7-9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claims 1-5, 7-9 and 14 are rendered uncertain by the phrase "A tea for treating dermatitis comprising: extracts obtained from lightyellow sophora root (*Sophora flacescens* Ait.), and isatis leaf (*Isatis tinctoria* L.)" in claims 1, 2, 4, 5, 8 and 9, and "extracts obtained from one, two or more medicinal herbs selected from the group consisting of Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, bikal skullcap, lithospermum, kudingcha, smartweed, and licorice" because it is unclear as to what Applicant considers "extracts" to be. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that no art rejection has been made because it is unclear as to the identity of each ingredient Applicant is claiming. The fact that no art rejection has currently been made does not indicate that no art exists nor does it mean that the claims would be allowable if Applicant were to overcome the objections and rejections above.

Response to Arguments

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 07/11/2007, with respect to the rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) as being anticipated by Ho et al. (A*, 5,466,443) have been fully

considered and are persuasive, with regards to the difference between isatis leaf and indigo. The rejection of claims 1-3 and 7 under 35 U.S.C. 102(b) has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
May 12, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655